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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,914	12/04/2003	Lawrence K. Pierce	1434-004	7565
32905	7590	05/24/2006	EXAMINER	
JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108				ROBINSON, KEITH O NEAL
ART UNIT		PAPER NUMBER		

1638
DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/727,914	PIERCE, LAWRENCE K.
	Examiner	Art Unit
	Keith O. Robinson, Ph.D.	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/15/2005</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to for the omission of "A" at the beginning of the sentence.

The claim should read: A seed [Seed] of celery line designated ADS-3,
representative seed of said line having been deposited under ATCC Accession No.
PTA-_____.

Claim 21 is objected to because the claim does not recite that the claimed plant has modified fatty acid or carbohydrate metabolism. The claim should read: A celery plant produced by the method of claim 20, wherein said plant has modified fatty acid metabolism or modified carbohydrate metabolism.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8, 9, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn hybrid celery seed and seed derived from said hybrid celery seed.

The specification does not describe the other celery plant or plants that are to be crossed with ADS-3 nor is there a description of their genetic, morphological, and/or

physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the ADS-3 celery plant and 50% of the alleles from the other celery plant. The ADS-3 celery plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the ADS-3 celery plant is not the same as the claimed ADS-3 celery plant, which would have 100% of its alleles. Furthermore, claim 9 reads on an additional generation of outcrossing to a non-ADS-3 celery parent so that seed with as little as 25% of the ADS-3 alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing ADS-3 with any celery plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids.

Claim 20 is drawn to a method of producing a celery plant with modified fatty acid metabolism or modified carbohydrate metabolism comprising transforming the celery plant of claim 2 with a transgene selected from a group of transgenes. The specification fails to provide support for the claimed transgenes; therefore, the claim lacks adequate written description.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

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subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Given the failure of the specification to describe the claimed hybrid plant, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph, first paragraph - Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to seed of celery line ADS-3, methods of using said seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then

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an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

It is noted that Applicants have deposited the seed of this invention (see page 31 of the specification), but this deposit statement is incomplete. There is no indication in

the specification as to the duration that the deposit will be maintained, the viability of the biological material at the time of deposit, or the replacement of inviable seeds.

Applicant is asked to make the required corrections.

Claims 8, 9, 20 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn hybrid celery seed and seed derived from said hybrid celery seed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification does give any guidance as to the other celery plant or plants that are to be crossed with ADS-3 nor is there any guidance as to their genetic, morphological, and/or physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the ADS-3 celery plant and 50% of the alleles from the other celery plant. The ADS-3

celery plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the ADS-3 celery plant is not the same as the claimed ADS-3 celery plant, which would have 100% of its alleles. Furthermore, claim 9 reads on an additional generation of outcrossing to a non-ADS-3 celery parent so that seed with as little as 25% of the ADS-3 alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing ADS-3 with any celery plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide any guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

Claim 20 is drawn to a method of producing a celery plant with modified fatty acid metabolism or modified carbohydrate metabolism comprising transforming the celery plant of claim 2 with a transgene selected from a group of transgenes. The specification fails to provide any guidance regarding the claimed transgenes; therefore, it would require undue trial and error experimentation for one skilled in the art to make and use the claimed invention.

There is no guidance in the specification regarding the plants claimed in claims 24-27 because they are produced by crossing the claimed invention, celery line ADS-3, with an undisclosed celery plant. Since there is no guidance provided for this plant, it

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would require undue trial and error experimentation for one of skill in the art to produce the claimed plants. While the introgression of single genes into plants for a desired trait is desirable and is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Browers et al (Biotechnology in Agriculture and Forestry, Vol. 2, Crops I, edited by Y.P.S Bajaj, Springer-Verlag, Berlin, Heidelberg, pp. 405-420, 1986) teach that breeding of celery leaves residual genetic variability within the variety and that the genetic base of celery is narrow, resulting in inbreeding depression (see page 406, fourth paragraph to page 407, end of first paragraph). Browers et al also teach that "little is understood about the genetic control of important horticultural traits" and that "Breeding is ... largely based on intuition and chance" (see page 407, fourth paragraph).

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that "Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it may not be useful

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because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlone, U.S. Patent 5,763,755, column 2, lines 11-14). The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F_2 or S_0 population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the trait of grain yield of the parental inbred lines of a inbred maize plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed maize plants and

methods of making a maize plant using a second or filial non-exemplified maize plant produced from Applicant's exemplified inbred maize plant.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue trial and error experimentation.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8, 9 and 24-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wolf et al (HortScience 28(7): 754-755, 1993). The claims read on celery plants produced by crossing the claimed invention with any celery plant wherein theoretically, due to segregation of alleles, the claimed plants would possess some, or all, of the traits expressed in the prior art.

White et al disclose celery plants wherein said celery plants have several of the same characteristics as those of celery line ADS-3 such as: days to maturity, cylindrical stalk shape, stalk conformation, petiole length at midpoint, petiole thickness, and moderate ribbing (see page 754, 3rd column, 1st and 2nd paragraphs).

White et al do not teach celery plants derived from the cross of celery line ADS-3 with another celery plant.

The celery plant or seed taught by the prior art differs from the claimed celery plant or seed in their method of making, namely by the use of different parental material. However, the method of making the claimed celery plant would not distinguish it from the prior art celery plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

9. Claims 1-7 and 10-23 are deemed free of the prior art given the failure of the prior art to reasonably teach or suggest celery line ADS-3 or methods of using said line.
10. No claims are allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

May 7, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

